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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,814	09/19/2002	Glen Patrick Martyn	GJE-6035	4398

23557 7590 02/09/2005

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EXAMINER

SPEAR, JAMES M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,814

Applicant(s)

MARTYN ET AL.

Examiner

James M Spear

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/30/03, 5/13/02.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claim 3 is objected to because of the following informalities: spelling "pollulan" or "pullulan"? Note that while claim 10 was amended claim 11 was not. Appropriate correction is required.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. US 4,623,394. See control, Table 1, No. 13, experiments 1 and 2. The control shows each element of applicants' claims. Nakumara et al shows that the current state of the art encompasses applicants' rapidly soluble, open matrix of a carbohydrate polymer, pullulan. A comparative example or control can be used to show what is or is not novel. Column 1, lines 35-41.

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5. Claims 1, 3, 4, 6-8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 08 291051. See Abstract. The reference shows a rapidly dissolving tablet comprised of the therapeutic agent dihydrocodeine phosphate wherein the binder can be pullulan. Excipients such as fillers and flavorings are further disclosed.
6. Claims 1, 4, 6-10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 91/09591. See examples 19-21, 23, 24-30 and 34, page 8, lines 1-10.
7. Claims 1, 2, 4-7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 96/40077. See example 5d.
8. Claims 1, 3, 4 and 6-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Iwatsuki et al US 5,064,057. See example 1, table 1.
9. Claims 1, 2 and 4-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Roser US 5,762,961. See example 1, table 1 samples 7 and 8.
10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Hussain et al reference US 5,704,297 shows a hydroxyethyl starch formulation that may be of interest. See column 2, lines 40-68.

Claims 1-11 are rejected.

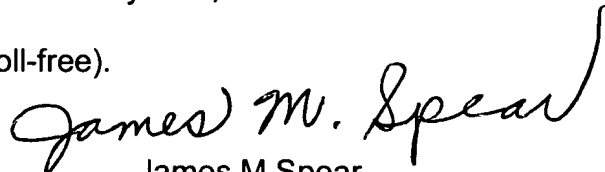
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272

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0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James M Spear
Primary Examiner
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February 6, 2005